AUG 1 2000

K000737

510(k) Summary of Safety and Effectiveness for
Xentek Medical, Inc. Coaxial Dialtor Set
(Prepared in accordance with 21 CFRPart 807.92)
Date 10/1/99

(1) **Submitter:** Xentek Medical, Inc.
P.O. Box 389
Athens, TX 75751
903.675-1429
Contact Person: Jim Eddings

(2) **Device Name:** Coaxial Dilator Set
Trade Name: No proprietary name has been established.
Classification Name: Dilator, Vessel, for percutaneous catheterization
Classification Code: DRE

(3) **Substantial Equivalency:** Xentek Medical, Inc.'s tearaway introducer is substantially equivalent to Tearaway Introducers from:
Medamicus
Boston Scientific
Bard

(4) **Device Description and Intended Use:** The materials of construction are consistent with Coaxial Dilator Sets presently in commercial distribution. The product is available in 4F, 4.5F and 5F. The length is approximately 4.0 inches.

(5) **Technological Characteristics:** Xentek Medical's coaxial dilator sets have the same indications for use and are otherwise technically the same as the predicate devices.

(6) **Non-Clinical Tests:** The results of these tests demonstrated that the functionality and performance characteristics of the introducers are comparable to the currently marketed introducers. Tests performed include tensile strength.

(7) **Conclusions:** Based on the information presented in this premarket notification 510(k), Xentek Medical's coaxial dilator sets are considered substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Mr. James R. Eddings
President
Xentek Medical, Inc.
6136 FM 1616
P.O. Box 389
Athens, TX 75751

Re: K000737
Trade Name: Coaxial Dilator Set
Regulatory Class: II (two)
Product Code: DRE
Dated: July 10, 2000
Received: July 11, 2000

Dear Mr. Eddings:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): _____

Device Name: Coaxial Dilator Set

Indications For Use:

These Coaxial Dilator Sets are intended to introduce up to a 0.038 in. guidewire or catheter into the vascular system following a small gauge needle stick.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000737

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)